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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/087,014	03/01/2002	Henrik Hansen	12013/59301	2646
23838	7590	04/21/2005	EXAMINER	
KENYON & KENYON 1500 K STREET, N.W., SUITE 700 WASHINGTON, DC 20005			TSOY, ELENA	
			ART UNIT	PAPER NUMBER
			1762	
DATE MAILED: 04/21/2005				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/087,014

Applicant(s)

HANSEN ET AL

Examiner

Elena Tsoy

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 3/02/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16, 18-29 is/are pending in the application.
- 4a) Of the above claim(s) 20-24 and 29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16, 18, 19 and 25-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 2/25/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

Amendment filed on March 2, 2005 has been entered. Claims 1-16, 18-29 are pending in the application. Claims 20-24 and 29 are withdrawn from consideration as directed to a non-elected invention.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 12, 13 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201) for the reasons of record as set forth in Paragraph No. 2 of the Office Action mailed on December 3, 2004.

3. Claim 3 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Yalkowsky (US 4,489,026) for the reasons of record as set forth in Paragraph No. 3 of the Office Action mailed on December 3, 2004.

4. Claim 4 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Forster (US 4,581,242) for the reasons of record as set forth in Paragraph No. 4 of the Office Action mailed on December 3, 2004.

5. Claims 5, 6, 8, 14-16, 18, 25-28 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Iguchi et al (US 5,756,553) in view of Forster (US 4,581,242) and Schwartz et

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al (US 6,607,598) for the reasons of record as set forth in Paragraph No. 5 of the Office Action mailed on December 3, 2004.

6. Claims 7, and 9-11 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Dunajtschik (US 4,586,457) for the reasons of record as set forth in Paragraph No. 6 of the Office Action mailed on December 3, 2004.

7. Claim 19 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Vickery (US 3,991,750) in view of Lucke (5,302,201), further in view of Fernandez et al (US 3,696,188) for the reasons of record as set forth in Paragraph No. 7 of the Office Action mailed on December 3, 2004.

Response to Arguments

8. Applicants' arguments filed March 2, 2005 have been fully considered but they are not persuasive.

(A) Applicants argue that Claims 1-4 are patentable over the cited references at least because neither Vickery nor Lucke disclose or suggest "placing therapeutic into the drum by moving the therapeutic through a channel positioned in the drum, the channel containing a plurality of orifices", and the Office action provides no evidence of motivation for making a combination of Vickery and Lucke. Lucke does not teach or suggest moving a therapeutic through a channel in a rotating drum. While the word pharmaceutical is used at col. 4 line 22 of Lucke, it is being used to refer to the tablets being coated by the process of Lucke, not the content of the coating being applied. Thus, as there is no therapeutic being applied in Lucke, Lucke does not disclose or suggest the recited language.

The Examiner respectfully disagrees with this argument. In contrast to Applicants' argument, Lucke teaches that devices with a drum for coating material which rotates about an axis, in particular for film and/or sugar-coating, are used in the pharmaceutical industry mainly for coating cores (See column 1, lines 6-10, 33-40). Lucke further teaches that the device of his invention meets all extended requirements which are given in the production of pharmaceutical coatings (See column 4, lines 20-23); and the device ensures a simple optimization of the sugar-coating and film-coating processes (See column 4, lines 23-25). Thus, Lucke does teach moving a pharmaceutical coating (claimed therapeutic) material through a channel in a rotating drum

Vickery teaches spraying a therapeutic in a solvent carrier (i.e. pharmaceutical coating) over the tumbling cores in a rotatable drum to make coated pellets.

One of ordinary skill in the art at would have reasonable expectation of success of using teaching of Lucke to modify a rotary drum Vickery or use a rotary drum of Lucke containing a plurality of orifices, where a pharmaceutical coating material is applied by moving the coating materials through a carrier positioned in the drum and having a plurality of spraying nozzles, and spraying the coating materials through the nozzles, and the applied coating is dried by blowing a gas with the expectation of providing the desired high quality of coated cores, as taught by Lucke.

Therefore, the Office action provides clear evidence of motivation for making a combination of Vickery and Lucke.

(B) Applicants argue that Claims 12 and 13 are patentable over the combination of Vickery and Lucke because neither reference discloses or suggests drawing a compressible fluid into the drum" as in claim 12 and "heating the rotatable drum after spraying the therapeutic into the drum," as in claim 13. Lucke, at col. 7 lines 30-38, the portion cited by the Office action to

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reject claim 12, does not disclose or suggest drawing a compressible fluid into a drum. Rather, in Lucke, the compressible fluid is pushed through the drum 58. As for claim 13, there is no disclosure or suggestion to perform the affirmative step of heating the rotatable drum after spraying therapeutic into the drum. The portion of Vickery cited by the Office action heats the bed while coating is ongoing, not afterwards.

The Examiner respectfully disagrees with this argument. Lucke teaches that coating cores in rotary drums containing a plurality of orifices 51 in the wall, where a pharmaceutical coating material is applied (See column 4, lines 21-22) by moving the coating materials through a carrier (channel) 54 positioned in the drum and having a plurality of spraying nozzles (orifices) 53, spraying the coating materials through the nozzles 53 (See Fig. 4; column 7, lines 30-38) and the applied coating is dried by blowing a gas (claimed drawing a compressible fluid), allows to achieve high quality of coated cores (See column 4, lines 34-35). And Vickery teaches that the solvent can be removed using hot air (drying) after spraying a therapeutic in a solvent carrier over the tumbling cores (See column 9, lines 10-13; column 14, lines 10-11).

Therefore, Claims 12 and 13 are not patentable over the combination of Vickery and Lucke because references disclose drawing a compressible fluid into the drum" as in claim 12 and "heating the rotatable drum after spraying the therapeutic into the drum," as in claim 13.

(C) Applicants argue that none of references discloses or suggests placing an implant with a masking material into the drum of a pan coater. Schwartz regards the use of an air suspension type device, one that does not include any type of pan coater.

The Examiner respectfully disagrees with this argument. Masking techniques for partial coating of medical implants to result in coating of predetermined segments are well known in the art, as evidenced by Schwartz et al (See column 11, line 67; column 12, lines 1-2). One of ordinary

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skill in the art at would understand that masking techniques would result in partial coating no matter what kind of coating technique is used as long as portion of a core is not available to be covered by coating material.

(D) Applicants argue that claims 7-11 are patentable over the references at least because there is no motivation to combine the references. In fact, the references teach away from the suggested combination. Should the drum 48 of Lucke be sealed in a manner taught by Dunajtschik (at col. 7, lines 14-26), the Lucke system would not function as the segments 51 would not be able to allow air to exit the drum. Without this venting, Lucke simply wouldn't work and could even fail if pressure inside the drum exceeded its design limits.

The Examiner respectfully disagrees with this argument. First of all, the segments 51 would not be sealed themselves but only against the atmosphere so that the process can run with recirculated air within the surrounding housing since Dunajtschik teaches that it is possible in principle to completely seal the inner space of the coating drum 2 against the atmosphere, so that either directly or within the surrounding housing the process can run with recirculated air (See column 7, lines 14-26).

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elena Tsoy whose telephone number is (571) 272-1429. The examiner can normally be reached on Mo-Thur. 9:00-7:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on (571) 272-141523. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ELENA TSOY
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Primary Examiner
Art Unit 1762

April 18, 2005